

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS**

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IN RE PHARMACEUTICAL  
INDUSTRY AVERAGE  
WHOLESALE PRICE LITIGATION

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) MDL No.1456  
)  
) Master File No. 01-CV-12257-PBS  
) Subcategory No. 06-CV-11337-PBS  
)

THIS DOCUMENT RELATES TO:  
*United States of America ex rel. Ven-A-Care*  
*of the Florida Keys, Inc., et al. v.*  
*Boehringer Ingelheim Corporation, et al.,*  
Civil Action No. 07-10248-PBS

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) Judge Patti B. Saris  
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) Magistrate Judge Marianne B. Bowler  
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)  
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**CORRECTED BOEHRINGER INGELHEIM CORPORATION AND  
BOEHRINGER INGELHEIM PHARMACEUTICAL INC.  
LOCAL RULE 56.1 STATEMENT OF UNDISPUTED MATERIAL FACTS  
IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT**

Pursuant to Local Rule 56.1, Boehringer Ingelheim Corporation and Boehringer Ingelheim Pharmaceuticals, Inc. submit this statement of the material facts of record as to which there is no genuine issue to be tried in support of Boehringer Ingelheim Corporation's and Boehringer Ingelheim Pharmaceuticals, Inc.'s Motion for Summary Judgment.

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**I. BIC, BIPI And Roxane Were Separate Legal Entities With Distinct Business Purposes**

1. Boehringer Ingelheim Corporation (“BIC”) is incorporated in Nevada and has its principal place of business in Ridgefield, Connecticut. BIC serves as the parent company of Roxane, BIPI and several other U.S. subsidiaries. (United States’ First Amended Complaint ¶ 13 (“First Am. Comp.”); Tab 15, McIntyre Dep. 22-23; Tab 32, RLI-ORG00000016 (Jan. 1998 Organization Chart); Tab 33, RLI-ORG00000023 (Jan. 2000 Organization Chart))

2. BIC is largely a holding company with very few employees. (Tab 24, Tetzner Dep. 64; Tab 15, McIntyre Dep. 22-23; Tab 2, 10/31/08 Berkle Dep. 29-30; Tab 32, RLI-ORG00000016 (Jan. 1998 Organization Chart; Tab 33, RLI-ORG00000023 (Jan. 2000 Organization Chart))

3. BIC has never owned, manufactured, marketed, or sold any pharmaceutical products and has no active business of its own. (Tab 15, McIntyre Dep. 22-23; Tab 14, 5/31/07 Marsh Dep. 21)

4. BIC has its own Board of Directors and officers. (Tab 2, 10/31/08 Berkle Dep. 325, 358-362)

5. Boehringer Ingelheim Pharmaceuticals, Inc. (“BIPI”) is a wholly-owned subsidiary of BIC, and is also located in Ridgefield, Connecticut. It was incorporated under the laws of Delaware. (Tab 29, 5/11/07 Waterer Dep. 523; Tab 14, 5/31/07 Marsh Dep. at 21; First Am. Comp. ¶ 14) BIPI is in the business of marketing and selling brand-name, patent-protected pharmaceutical products. (Tab 2, 10/31/08 Berkle Dep. 29; Tab 15, McIntyre Dep. 21)

6. BIPI has its own FDA labeler code that is assigned to the BIPI-labeled products it markets and sells. BIPI’s labeler code is 00597. (Tab 35, Food & Drug Administration

National Drug Code Directory, *available at*

<http://www.accessdata.fda.gov/scripts/cder/ndc/queryndcfn.cfm>)

7. BIPI has its own marketing department and budget. (Tab 2, 10/31/08 Berkle Dep. 323-24)

8. BIPI has its own sales force that promotes BIPI products. (*Id.*)

9. BIPI has its own customers that it contracts with and invoices. (*Id.* 313-14, 322)

10. Roxane Laboratories, Inc. (“Roxane”) was first organized in 1885 as Columbus Pharmacal, a small, regional pharmaceutical manufacturer. Columbus Pharmacal was purchased by Philips of the Netherlands, and the name was changed from Columbus Pharmacal to Philips Roxane. (Tab 36, “Roxane Laboratories Oral Solid Dosage Facility Expansion, Columbus, OH”, *available at* <http://www.pharmaceutical-technology.com/projects/roxane/>) It was not until 1978 that Roxane became part of the Boehringer Ingelheim family. (Tab 37, “Boehringer Ingelheim in the United States is available at <http://www.us.boehringer-ingelheim.com/about-us/company-history.html>.; Tab 19, 10/11/05 Powers Dep. 198)

11. Roxane was a Delaware corporation during the relevant timeframe, and is headquartered in Columbus, Ohio. (Tab 38, RLI-AWP-00000001-00000069 (1996-2004 Roxane Laboratories, Inc. Corporate Data Sheets) (Roxane Corporate Data))

12. In April 2005, Roxane Laboratories, Inc. changed its name to Boehringer Ingelheim Roxane, Inc. (“BIRI”). (Roxane’s Answer to United States’ 1st Am. Compl. at 1, n.1; Tab 39, RLI-TX 7922-7923 (Roxane Reorganization Employee Announcement); Tab 40, RLI-AWP-00104259-62 (9/15/04 Reorg Letter) BIRI remains a Delaware corporation. BIRI continues to manufacture pharmaceutical products. (*Id.*) At the same time, a new entity, Roxane

Laboratories, Inc., a Nevada corporation, was incorporated. (*Id.*) As of that time, the new Nevada corporation (“RLI Nevada”) assumed responsibilities for sales and marketing of pharmaceutical products sold under the Roxane tradename. (*Id.*)

13. At all times relevant to this litigation, Roxane was a wholly-owned subsidiary of BIC. (Tab 29, 5/11/07 Waterer Dep. 523)

14. Roxane had its own employees, whom it retained the ability to hire and fire and to whom it offered its benefits plans that were different than those of its affiliates. (Tab 41, RLI-TX 17676-78 (Roxane Reorganization Human Resources Presentation))

15. Roxane has its own separate line of Roxane-labeled products that it marketed under its own name and labeler code. Currently, the Roxane product line consists of roughly 400-500 NDCs. (Tab 6, 5/30/07 DeCapua Dep. 167; Tab 13, 6/27/02 Marsh Dep. 117; Tab 2, 10/31/08 Berkle Dep. 320-21)

16. Roxane has always been primarily focused on marketing multi-source products. Until 2001, Roxane also marketed a small line of brand and branded generic products. (Tab 2, 10/31/08 Berkle Dep. 30-31; Tab 14, 5/31/07 Marsh Dep. 28-29; Tab 6, 5/30/07 DeCapua Dep. 15-16; *infra* ¶ 81)

17. Roxane promotes its products primarily based on price and service to wholesalers and pharmacies. (Tab 29, 5/9/07 Waterer Dep. 102-103; Tab 29, 5/11/07 Waterer Dep. 538-540) Roxane had its own customers with whom it negotiated and entered into contracts. (Tab 29, 5/11/07 Waterer Dep. 547-51, 558-59)

18. Roxane has its own FDA labeler code, which is 00054. (Tab 18, 7/26/07 Paoletti Dep. 200)

19. Sales and marketing practices for brand and generic products are very different based on the nature of each market. (Tab 2, 10/31/08 Berkle Dep. 321; Tab 29, 5/9/07 Waterer Dep. 199-200; Tab 26, 10/24/01 Waterer Dep. 142-143)

20. Brand drugs are marketed mainly to physicians, based upon their clinical benefits. (Tab 26, 10/24/01 Waterer Dep. 142; Tab 29, 5/9/07 Waterer Dep. 199-200) This is because brand drugs are patent protected, so as long as a prescription is written for that drug, it will be dispensed. (Tab 26, 10/24/01 Waterer Dep. 142-143) Multisource generic drugs are marketed mainly to wholesalers and retail pharmacies based on service and price. (Tab 2, 10/31/08 Berkle Dep. 322; Tab 29, 5/9/07 Waterer Dep. 199-200, *supra* ¶ 17)

## **II. Roxane Respected All Corporate Formalities And Maintained Independent Financial Records And Sufficient Capitalization.**

### **(a) Roxane Had a Fully-Functioning Board of Directors.**

21. Roxane had its own Board of Directors. From 1996 until 2005, Roxane's Board ranged in size from three to five directors, and included the following individuals: Werner Gerstenberg, Gerald Wojta, Phillip Franks, Walter Poerschman, Sheldon Berkle, Martin Carroll, and Robert Fromuth. (Tab 38, RLI-AWP-00000001-00000069 (Roxane Laboratories, Inc. Corporate Data Sheets) (Roxane Corporate Data))

22. In accordance with its bylaws and Delaware law, Roxane's Board acted through unanimous written consent, in lieu of meetings, to choose officers, directors, a chairman of the board, and to transact other company business. Roxane maintained written records of the Board's bylaws and unanimous consents. (Tab 42, BOEH04600117-21, BOEH04600151-54, BOEH04600159-67, BOEH04600197-09, BOEH04600226-47, BOEH04600248-52; BOEH04600254-63, BOEH04600267, BOEH04600292-94, BOEH04600302-06, BOEH04600326-28, BOEH04600330-39, BOEH04600363-77, BOEH04600382-85,

BOEH04600392-97, BOEH04600413-15, BOEH04600430-35, BOEH04600465-77, BOEH04600504-07, BOEH04600521-29, BOEH04600533-36, BOEH04600538-44, BOEH04600609-14 (Select Roxane Board of Directors Unanimous Written Consents 1996-2005) (Roxane Unanimous Consents))

23. Roxane's Board approved its bylaws. (Tab 42, BOEH04600226-47 (Roxane Unanimous Consents))

24. Roxane's Board approved financial reports and budgets. (Tab 42, BOEH04600159-67, BOEH04600197-06, BOEH04600254-63, BOEH04600302-06, BOEH04600330-39, BOEH04600363-68, BOEH04600392-97, BOEH04600430-35, BOEH04600465-77, BOEH04600609-14 (Roxane Unanimous Consents))

25. Roxane's Board approved dividend payments to its parent company, BIC. (Tab 42, BOEH04600117-21, BOEH04600292-94, BOEH04600326-28, BOEH04600413-15 (Roxane Unanimous Consents))

26. Roxane's Board approved decisions to file law suits. (Tab 42, BOEH04600151-54 (Roxane Unanimous Consents))

27. Roxane's Board approved decisions to enter co-promotion agreements, and to acquire and divest drugs. (Tab 42, BOEH04600248-52, BOEH04600369-74, BOEH04600375-77 (Roxane Unanimous Consents))

28. In 2005, Roxane's Board approved of the decision to restructure the company into two separate corporations, one for sales and marketing, and one for manufacturing. (Tab 42, BOEH04600504-07, BOEH04600521-29, BOEH04600533-36, BOEH04600538-44 (Roxane Unanimous Consents))

29. Roxane's Board appointed officers. (Tab 42, BOEH04600159-67 (1996); BOEH04600197-06 (1997), BOEH04600207-09 (1997); BOEH04600254-63 (1998); BOEH04600267 (1998); BOEH04600302-06 (1999); BOEH04600330-33 (2000); BOEH04600363-68 (2001); BOEH04600392-97 (2002); BOEH04600382-85 (2002); BOEH04600430-35 (2003); BOEH04600465-77 (2004); BOEH04600609-14 (2005) (Roxane Unanimous Consents))

30. Gerald Wojta was President and COO of Roxane until 1997. Following Wojta's departure, Werner Gerstenberg served as President and COO of Roxane from 1997 until 2002. Roxane's Board then appointed Robert Fromuth as President and COO, who held that position from 2002 until the 2005 split of Roxane. (Tab 38, RLI-AWP-00000058-67, RLI-AWP-00000016-58, RLI-AWP-00000001-16 (Roxane Corporate Data); Tab 42, BOEH04600207-09, BOEH04600382-85 (Roxane Unanimous Consents))

**(b) Roxane maintained separate financial records.**

31. Roxane's finances were accounted for separately and independently from its parent and affiliates, and Roxane kept its own separate financial records and statements. (Tab 15, McIntyre Dep. 202; Tab 43, BOEH04600203-05 (1996 Commentary); Tab 44, BOEH02541150-69 at 54, 60 (Commentary 1997 Actual); Tab 45, BOEH02541103-22 at 06, 12 (Commentary 1998 Year End Actual); Tab 46, BOEH02584571-97 at 76, 94 (Commentary 1999 Budget 1999 Actual); Tab 47, BOEH02687778-03 at 81, 02 (Commentary 2000 Target 2000 Actual); Tab 48, BOEH02675446-72 at 49, 71 (Commentary To The Financial Statements For Year End 12/31/01); Tab 49, BOEH00147729-58 at 33, 57 (2002 Year-End Financial Commentary); Tab 50, BOEH02675333-62 at 37, 53 (Roxane Labs, Inc. Year End 2003 & Commentary); Tab 51, BOEH04295701-32 at 25, 29 (Roxane Labs, Inc. Year End 2004 &



Commentary); Tab 52, BOEH02522567-99 at 91, 95 (Boehringer Ingelheim Roxane, Inc. and Roxane Laboratories, Inc. 2005 Year End Commentary))

32. During the relevant time period, a separate entity within the BIC corporate group, BI Services Center, Inc. (“BISC”) provided transactional financial services for BIC’s subsidiaries, such as accounts payable, accounts receivable, payroll, and customer service. (Tab 15, McIntyre Dep. 37-38, 41)

33. As part of the centralized financial services, BIC and its subsidiaries used a zero balance cash management system. Each legal entity had its own bank account, and at the end of each day, the money from each entity’s account was swept into a combined account so it could be invested on behalf of the entities. Records were kept tracking the amount that each individual affiliate contributed or withdrew from the investment account. (*Id.* 162-163).

34. Through the central cash management system established at the BISC, inter-company loans and short term advances to affiliates were made among BIC and its subsidiaries. The loans and advances were accounted for and tracked by the BISC through internal accounting records. (*Id.* 126-127, 160-162).

35. For loans and advances, the borrowing company paid interest to the lending company at a rate of LIBOR plus .25%. (*Id.* 126-127).

**(c) Roxane was sufficiently capitalized at all times.**

36. Roxane’s business consistently generated income and it maintained substantial retained earnings. Roxane never needed to use any funds from its capital stock or its additional paid-in capital, and the balances of each remained the same over time. Between 1995 - 2005, Roxane had an average annual net income of \$37,964,000. During that same period, it had average annual retained earnings of \$146,165,182. (Tab 42, BOEH04600164-67, BOEH04600102-06, BOEH04600258-63, BOEH04600305-06, BOEH04600335-36,

BOEH04600367-68, BOEH04600396-97, BOEH04600434-35, BOEH0460046569-71, BOEH04600613-14 (Roxane Unanimous Consents))

37. Roxane always had sufficient working capital to pay for its day-to-day obligations, such as bills, vendors, employees, ingredients and raw materials. (Tab 15, McIntyre Dep. 192-194).

38. Roxane's Board of Directors authorized dividend payments to be made to its parent corporation, BIC, based on the amount of its retained earnings and income. The amount of Roxane's dividend payment would increase when Roxane's income increased. (*Id.* 190-191; (Tab 42, BOEH04600117-21, BOEH04600292-94, BOEH04600326-28, BOEH04600413-15 (Roxane Unanimous Consents))

39. Roxane continued to be sufficiently capitalized after all of its dividend payments, as indicated by the company's continued positive retained earnings and positive working capital. (Tab 15, McIntyre Dep. 192; *see also* ¶ 36, *supra.*)

40. Roxane also held substantial assets in its own name, such as its manufacturing plant and equipment, inventories, and the rights, title and interest in its line of products. (Tab 44, BOEH02541150-69 at 11-12 (Commentary 1997 Actual); Tab 49, BOEH00147729-58 at 26-27 (2002 Year-End Financial Commentary); Tab 53, BOEH01046045-6092 (Elan Asset Purchase Agreement))

### **III. The Interactions And Relationships Between Roxane, BIPI And BIC Were Appropriate And Typical Of Normal Parent, Subsidiary And Affiliate Relationships.**

#### **(a) Inter-company transactions were conducted on arms-length terms**

41. Starting in 1993, BIPI contracted with Roxane to manufacture certain products, including Atrovent UDV. (Tab 15, McIntyre Dep. 80-81)

42. A 1993 written Contract Manufacturing Agreement provided the terms under which Roxane manufactured products for BIPI. (*Id.* 81, 203-204; Tab 54, McIntyre Ex. 29, BOEH04689322-32 (1993 Contract Manufacturing Agreement) (1993 Contract)) The contract had a ten year renewable term. (Tab 15, McIntyre Dep. 81-82; Tab 54, McIntyre Ex. 29, BOEH04689322-32 at 23 (1993 Contract))

43. In 2005, after the split of Roxane's marketing/sales and manufacturing businesses, BIRI and BIPI entered into a new written manufacturing contract. (Tab 15, McIntyre Dep. 204-205; Tab 55, McIntyre Ex. 30, BOEH04689307-21 (2005 BIRI/BIPI Contract Manufacturing Agreement) (2005 BIRI/BIPI Contract)) At the same time, BIRI and Roxane entered into a written contract manufacturing agreement containing the same terms. (Tab 15, McIntyre Dep. 207-208; Tab 56, McIntyre Ex. 31, BOEH04689293-306 (2005 BIRI/RLI Contract Manufacturing Agreement) (2005 BIRI/RLI Contract)) The 2005 contracts provided that BIPI and RLI would each pay BIRI its cost plus 10% for manufacturing drugs. (Tab 15, McIntyre Dep. 205, 208; Tab 55, McIntyre Ex. 30, BOEH04689307-21 at 15 (2005 BIRI/BIPI Contract); Tab 56, McIntyre Ex. 31, BOEH04689293-306 at 99 (2005 BIRI/RLI Contract))

44. BIPI was originally charged a set price per product under the 1993 agreement. (Tab 54, McIntyre Ex. 29, BOEH04689322-32 at 26, 32 (1993 Contract)) In 2001, BIPI began being charged on a "cost-plus" basis. Roxane's costs included ingredient costs, labor and overhead, and then a profit percentage was added to the cost. (Tab 15, McIntyre Dep. 82-86) The profit margin Roxane received on its contract manufacturing services under the cost-plus terms put in place in 2001 was later validated as an arms-length rate by a third-party consultant

who performed a study in 2004 of pharmaceutical manufacturing contracts between comparable companies and the profit margins those contracts contained. (*Id.* 87-88, 206-207)

45. For a period of time between 1996 and 2001, Roxane licensed a BIPI-developed drug called Viramune, which it marketed and sold as part of its HIV and palliative care specialty line. (*Id.* 156-157) Roxane booked the sales for Viramune and paid BIPI an 11% royalty pursuant to a written licensing agreement. (*Id.* 157, 172-173)

46. Roxane also licensed a product called Mexilitine from BIPI for a period of time, and paid an 11% royalty rate pursuant to a written licensing agreement. (Tab 57, BOEH04689278-92 at 285 (1995 BIPI/Roxane Mexilitine License Agreement))

47. Roxane paid the same 11% royalty for the right to market its generic ipratropium bromide under BIPI's NDA for Atrovent. (Tab 15, McIntyre Dep. 72-73)

48. The 11% royalty Roxane paid had been previously validated by a third-party consultant as an arms-length amount. (*Id.*)

**(b) Shared services were appropriately accounted for between the companies.**

49. Certain BIPI departments provided shared services at various times, including accounting, tax, legal, IT and contract administration. (Tab 15, McIntyre Dep. 38-41, 48-49; Tab 20, Russillo Dep. 273-274). Roxane was charged back and paid for the value of the services it used. (Tab 15, McIntyre Dep. 34, 37, 40, 49; Tab 20, Russillo Dep. 271-274)

50. At the beginning of each year, each department providing shared services would develop an operating budget and present it for approval to each subsidiary. Based on historical averages, an estimate would be made for how much work (*e.g.*, how many hours for legal services) each entity was predicted to use. Each legal entity was charged at a rate that made sense for that service (*e.g.*, hours for legal work). The estimated work and actual work used

by each entity was tracked throughout the year so that by the end of the year, the actual charges for each subsidiary could be reconciled (Tab 15, McIntyre Dep. 51-52)

51. In addition to shared services, a business unit concept was put in place to coordinate high level strategic oversight of BIPI and Roxane's common business areas for a period of time before Roxane divested its few brand products. Sheldon Berkle, a BIPI employee and Roxane board member, was designated as Vice-President of the Business Unit. (Tab 1, 1/27/05 Berkle Dep. 63-64; Tab 2, 10/31/08 Berkle Dep. 186-87) In this role, Mr. Berkle provided only strategic oversight, and was not involved in the day-to-day operations of Roxane. (*Id.*)

#### **IV. Roxane Controlled Its Day-to-Day Business Operations, Including The Pricing And Marketing Of Its Products.**

##### **(a) Marketing and Pricing of Multisource Generic Products**

52. Roxane had its own marketing and sales departments which were responsible for promoting its products. (Tab 2, 10/31/08 Berkle Dep. 324; Tab 22, 8/5/08 Shaffer Dep. 380; Tab 9, 11/18/05 Feldman Dep. 76; Tab 1, 1/27/05 Berkle Dep. 25; Tab 58, D0530608 (2003 Multisource Sales & Marketing Organizational Chart); Tab 59, RLI-ORG00000080 (1996 Budget Organizational Chart); Tab 60, RLI-ORG00000017 (Jan. 1998 Organizational Chart))

53. Judy Waterer began as Roxane's Manager for Multisource Program Development in 1996. In this position, Waterer was responsible for Roxane's multisource marketing activities, including launches, training sales representatives, advertising, and pricing. (Tab 26, 10/24/01 Waterer Dep. 31-34) In the early 2000s, Lesli Paoletti, a member of the marketing department, took over many of these responsibilities from Ms. Waterer. (Tab 18, 7/26/07 Paoletti Dep. 15-16; Tab 29, 5/9/07 Waterer Dep. 38, 64-65; Tab 29, 5/10/07 Waterer Dep. 282-283)

54. Roxane's multisource marketing department recommended the initial launch prices, including AWP, WAC, and direct price for Roxane's generic drugs. The marketing department was also responsible for developing and recommending changes to these prices for Roxane's generic drugs. In coordination with the contracts department, the marketing department developed pricing guidelines that established the range of contract prices that could be offered to customers and would assist in developing prices for bids outside of the pre-established grid. (Tab 27, 4/1/03 Waterer Dep. 517-518; Tab 29, 5/11/07 Waterer Dep. 566-567; Tab 31, 12/12/08 Waterer Dep. 47-49; Tab 18, 7/26/07 Paoletti Dep. 110-111; Tab 7, 6/25/02 Feldman Dep. 48, 56, 79-80; Tab 9, 11/18/05 Feldman Dep. 49-50; Tab 30, 7/24/07 Waterer Dep. 869-871; Tab 19, 10/11/05 Powers Dep. 51-52; Tab 16, 9/20/05 Paoletti Dep. 32)

55. The marketing department's pricing recommendations were circulated to various Roxane employees for information and sign-off purposes. The positions and particular individuals included changed over time, but generally included some combination of the product manager, director of multisource marketing, a member of the finance department, a member of the contracts department, a member of the sales department, and someone in senior management at Roxane, such as Roxane's Vice-President of Sales and Marketing. Examples of Roxane employees in those positions include Lesli Paoletti, Judy Waterer, John Swartz, John Powers, Rich Feldman, and Ed Tupa. (Tab 17, 11/30/05 Paoletti Dep. 16-17, 90-91; Tab 28, 11/28/05 Waterer Dep. 168 (marketing would recommend the pricing and it would get routed and approved by management); Tab 26, 10/24/01 Waterer Dep. 34-38 (price routing forms included marketing management, sales management, contracts management, and sometimes member of senior management, such as Gerald Wojta, President of Roxane); Tab 29, 5/11/07 Waterer Dep. 602-603, 619-621, 624) Other than being circulated to this core set of Roxane

employees, prices for Roxane's multisource drugs never went to a formal pricing committee for approval. (Tab 20, Russillo Dep. 147-148)

56. Until 1998, Ms. Waterer reported to Ed Tupa, Vice-President of Marketing at Roxane. (Tab 26, 10/24/01 Waterer Dep. 57) While Mr. Tupa had a functional reporting relationship to Mr. Berkle, Vice President of the Business Unit Ethical Pharmaceuticals, Mr. Tupa led Roxane's marketing department, with Ms. Waterer handling the day-to-day marketing and pricing activities for Roxane's products. Mr. Berkle's role was limited to very high level strategic oversight. (Tab 26, 10/24/01 Waterer Dep. 31-34; Tab 2, 10/31/08 Berkle Dep. 50-51; *id.* 76 ("I was not involved in the day-to-day operations of Roxane or in basically how they set their prices in general or how they marketed their generic drugs"); *id.* 125 ("In general I've said to you before that I really did not get involved in the details of pricing for the generic products within the Roxane line"); Tab 61, 10/31/08 Berkle Dep. Ex. 5, RLI-AWP-00162482-84 at 83 (5/3/96 Roxane Sales and Marketing Reorganization Announcement and Organizational Chart) (1996 Reorganization Announcement) ("The Roxane Marketing & Sales Department will be led by Mr. Edward Tupa, who currently has this responsibility."); Tab 62, RLI-ORG00000068 (Jan. 1998 Organigram); Tab 59, RLI-ORG00000080 (1996 Budget Organizational Chart))

57. Ed Tupa left his position as Vice President of Marketing in October 1998. Tom Russillo, who was the President of another BIC subsidiary, Ben Venue Laboratories, Inc. ("BVL"), took on the additional position of head of Multisource Marketing for Roxane at that time. (Tab 63, 10/31/08 Berkle Ex. 27 RLI-AWP-00161738-40 (10/23/98 Reorganization Memo); Tab 20, Russillo Dep. 23-26; Tab 32, RLI-ORG00000016 (Jan. 1998 Organigram)) Mr. Russillo reported to Werner Gerstenberg. (Tab 20, Russillo Dep. 29)

58. Ms. Waterer and others in the Roxane multisource marketing department began reporting to Mr. Russillo in this new role. (Tab 63, 10/31/08 Berkle Ex. 27 at RLI-AWP-00161738-40 (10/23/98 Memo); Tab 26, 10/24/01 Waterer Dep. 57; Tab 20, Russillo Dep. 49-50, 53-54; Tab 58, D0530608 (2003 Multisource Sales & Marketing Organizational Chart))

59. Mr. Russillo had worked in the generic pharmaceutical business for many years and Ben Venue's generic sales division, Bedford Laboratories, was very successful in the market. Thus, Mr. Russillo had extensive experience and expertise in marketing and selling generic drugs that he could bring to bear to help build Roxane's generic business. (Tab 20, Russillo Dep. 26, 202-203)

60. Mr. Russillo "ultimately managed" the pricing approval process for Roxane's multisource drugs from late 1998 forward. (*Id.* 53-54, 286) Ms. Waterer and the Roxane marketing department, however, continued to be responsible on a day to day basis for setting the AWP's for multisource products. (*Id.* 49-50, 54 ("For the most part, I would not be personally involved. Judy would propose an AWP; and for the most part, I would have approved it."); Tab 26, 10/24/01 Waterer Dep. 57, 168-170)).

61. Although Mr. Russillo was able to approve or disapprove AWP and price recommendations without further routing to other Roxane employees, Ms. Waterer continued to circulate price proposals to key Roxane employees. (Tab 29, 5/11/07 Waterer Dep. 596; *see also, e.g.*, Tab 64, RLI-AWP-00559612 (Feb. 19, 2002 Price Approval form); Tab 65, RLI-AWP-00081519 (April 1, 2002 Price Approval form); Tab 66, RLI-AWP-00083025-30 (Feb. 20, 2003 Price Approval form); Tab 67, BOEH01140848 (May 28, 2003 Price Approval



form); Tab 68, RLI-AWP-00082794-09 (June 4, 2003 Price Approval form); Tab 69, RLI-AWP-00081645-51 (July 2, 2003 Price Approval Email Chain))

62. Mr. Russillo generally did have to seek further approval from his superiors regarding Roxane multisource prices. Rather, at his discretion, he may have consulted Werner Gerstenberg, who was the President of Roxane. (Tab 20, Russillo Dep. 98)

63. After Roxane's management signed-off on initial prices or price changes for Roxane's generic products, someone from Roxane's marketing or trade relations departments would report the pricing information to third party compendia, such as First DataBank. (Tab 27, 4/1/03 Waterer Dep. 501-502, 581; Tab 29, 5/11/07 Waterer Dep. 682-86; Tab 17, 11/30/05 Paoletti Dep. 47-49; Tab 70, 5/10/07 Waterer Dep. Ex. 24 (Red Book 13858-59); Tab 71, 5/10/07 Waterer Dep. Ex. 25 (Red Book 13860-13864); Tab 72, 5/10/07 Waterer Dep. Ex. 26 (Red Book 13865-13867); Tab 73, 5/10/07 Waterer Dep. Ex. 27 (Red Book 13868-13870); Tab 74, 5/10/07 Waterer Dep. Ex. 29 (Red Book 13969-13971); Tab 75, 5/10/07 Waterer Dep. Ex. 30 (Red Book 13972-13974); Tab 76, 5/10/07 Waterer Dep. Ex. 31 (Red Book 13975-76); Tab 77, 5/10/07 Waterer Dep. Ex. 34 (Red Book 14071-14083); Tab 78, 5/10/07 Waterer Dep. Ex. 35 (Red Book 14084-14085); Tab 79, 5/10/07 Waterer Dep. Ex. 42 (Red Book 14185-14186); Tab 80, 5/10/07 Waterer Dep. Ex. 47 (Red Book 14205-14206); Tab 81, 11/17/04 Feldman Dep. Ex. 93 TXEX00520)

64. At times, Roxane received requests from third party compendia to verify its reported AWP's and WACs. Roxane's marketing department was responsible for reviewing the information and communicating any changes or corrections to the compendia. (Tab 29, 5/10/07 Waterer Dep. 455-458; Tab 18, 7/26/07 Paoletti Dep. 195-197; Tab 82, 5/9/07 Waterer Dep. Ex. 32 (Red Book 13977-14065))

65. Roxane had National Account Managers (“NAMs”) who handled day-to-day marketing and sales interactions with Roxane’s customers, including wholesalers and chains. (Tab 23, Sykora Dep. 200-202; Tab 8, 11/17/04 Feldman Dep. 86-87)

66. Based on their knowledge of market conditions, NAMs would provide the marketing department with recommendations for price changes as the competitive landscape for certain drugs changed. The marketing department would compile relevant information and develop a final pricing recommendation. (Tab 23, Sykora Dep. at 76-77; Tab 28, 11/28/05 Waterer Dep. at 32-35)

67. In June 1996, Roxane launched ipratropium bromide, a generic version of BIPI’s brand product Atrovent. (Tab 26, 10/24/01 Waterer Dep. 38-39; Tab 29, 5/10/07 Waterer Dep. 292-294; Tab 25, 10/18/05 Via Dep. 61)

68. Tom Via, a Roxane marketing employee, developed the marketing plan for ipratropium bromide. As part of that process, Mr. Via and Ed Tupa, Roxane’s Vice President of Sales and Marketing set the AWP, WAC, and direct prices for ipratropium bromide at the product’s launch. (Tab 25, 10/18/05 Via Dep. 154-155, 157, 163-165) The AWP for Roxane’s ipatropium bromide did not change from launch until the product was discontinued in 2004. (Tab 83, Roxane’s Second Supp. Objections and Answers to the Commonwealth’s First Set of Interrogatories (7/18/07) at 3)

69. Because BIPI had experience in the respiratory product market from its sales of Atrovent, as Roxane prepared to launch its generic product, BIPI shared information and expertise on a high-level about the respiratory drug market and current market conditions. No one from BIPI was involved in marketing details or price setting for Roxane’s ipratropium bromide. (Tab 1, 1/27/05 Berkle Dep. 28, 38, 72-73)

70. In 2000, Roxane sought to change the AWP on one of its multisource products, furosemide, due to customer complaints that it was out of line with the AWP for that drug in the rest of the market. (Tab 29 5/9/07 Waterer Dep. 75-76) Roxane's marketing and sales teams compiled supporting documentation for the AWP change, and the marketing department developed a price change recommendation for Mr. Russillo's review. (Tab 17, 11/30/05 Paoletti Dep. 141-145; Tab 29, 5/9/07 Waterer Dep. 201-202)

71. Mr. Russillo approved the marketing department's recommendation to increase furosemide's AWP. While Mr. Russillo did not believe he sought further approval for the furosemide price increase, he explained that if he had, he would have discussed the price change with Werner Gerstenberg, in his role as President and COO of Roxane. (Tab 20 Russillo Dep. 167-168, 174-75, 178-179, 191-192)

**(b) Marketing of Brand and Branded Generic Products**

72. Until the 2000-2001 timeframe, Roxane sold a small line of brand and branded generic drugs in addition to its main line of multisource generic drugs. These drugs included HIV and palliative care/pain products. (Tab 7, 6/25/02 Feldman Dep. 174; Tab 2, 10/31/08 Berkle Dep. 30-31; Tab 21, 5/21/08 Shaffer Dep. 54-55; Tab 84, RLI-ORG 00000083 (1999 Roxane Sales Org. Chart))

73. Branded generic drugs are generic drugs that have been given proprietary names beyond the chemical formulation (such as Roxicodone, Roxicet or Roxanol) and are marketed to physicians in the same manner as brand products. (Tab 2, 10/31/08 Berkle Dep. 31; Tab 3, 12/12/08 Carr Hall Dep. 74-75)

74. Roxicodone, Oramorph SR, and Roxanol -- three of the drugs at issue in this case -- were part of Roxane's branded generic palliative care line. (*See* United States' First Amended Complaint at ¶ 58; Tab 21, 5/21/08 Shaffer Dep. 55)

75. Roxane had its own marketing staff dedicated to promoting its brand and branded generic products that was separate from its multisource marketing team. The marketing staff reported to Gary Ellexson, Executive Director of Marketing RLI Brands. Mr. Ellexson reported to Ed Tupa, Vice President of Marketing at Roxane, until he left the company in October 1998. The marketing staff product managers were responsible for launching new products and Ed Tupa was involved in developing pricing for the brand/branded generic products. (Tab 29, 5/10/07 Waterer Dep. 254-56; Tab 5, 7/25/07 Ciarelli 33-34; Tab 4, 6/26/02 Ciarelli Dep. 30-31, 98; Tab 29, 5/10/07 Waterer Dep. 304; Tab 25, 10/18/05 Via Dep. 42-44, 50; Tab 21, 5/21/08 Shaffer Dep. 50; Tab 85, 5/21/08 Shaffer Dep. Ex. 10 (Oramorph SR Price Increase))

76. Roxane employees were responsible for providing its brand/branded generic prices to the pricing compendia. (*See, e.g.*, Tab 78, 5/10/07 Waterer Dep. Ex. 35 (Red Book 14084-85); Tab 77, 5/10/07 Waterer Dep. Ex. 34 (Red Book 14071-83); *see also* pricing communications listed in ¶ 63)

77. Roxane also had its own field sales force responsible for promoting its palliative care and HIV products, mainly to physicians, and they reported to Jerry Hart, as Director of RLI Brand Sales. (Tab 22, 8/5/08 Shaffer Dep. 363; Tab 86, RLI-ORG00000082 (1998 Roxane Sales Department Organization Chart)) In 1999, the palliative care and HIV divisions of the RLI Brand sales group split; the HIV group continued to report to Mr. Hart, and the palliative care group began reporting to Mark Shaffer as Director of Sales for Palliative Care. (Tab 21, 5/21/08 Shaffer Dep. 54; Tab 84, RLI-ORG00000083 (1999 Roxane Sales Department Organization Chart)) The HIV sales force had roughly 35-50 members, and the palliative care sales force had roughly 50 members. (Tab 25, 10/18/05 Via Dep. 87)

78. In late 1998, organizational changes were made to leverage the expertise and experience in marketing brand name products of several BIPI-based employees for the benefit of Roxane's brand and branded generic products, and certain Roxane employees in marketing and sales for branded generics began to report functionally to designated people at BIPI. (Tab 2, 10/31/08 Berkle Dep. 59-60). Specifically,

- Gary Ellexson, Director of Roxane's Branded and Specialty Marketing, began reporting to Greg Fulton, who became head of BIPI/RLI Branded Marketing. (Tab 63, 10/31/08 Berkle Dep. Ex. 27 at RLI-AWP-00161739 (10/23/98 Reorganization Memo); Tab 87, 1/27/05 Berkle Dep. Ex. 139, TXEX00810 (Roxane Laboratories, Inc. Budget 1999 Organizational Chart) (Budget 1999 Org. Chart)) Roxane's Branded Marketing staff continued to report to Ellexson. (*Id.*)
- Jerry Hart, Director of Roxane Sales, began reporting to Jim King, who became head of BPI/RLI Branded Sales. Roxane's field sales force continued to report to Hart. (Tab 63, 10/31/08 Berkle Dep. Ex. 27 at RLI-AWP-00161739 (10/23/98 Reorg. Memo); Tab 87, 1/27/05 Berkle Dep. Ex. 139, TXEX00810 (Budget 1999 Org. Chart))
- BIPI and RLI Contract Administration continued to have departments at both BIPI and Roxane, but management was streamlined. (Tab 63, 10/31/08 Berkle Dep. Ex. 27 at RLI-AWP-00161740 (10/23/98 Reorganization Memo)) John Powers, Roxane's Director of Contracts, began reporting to Gregg Ciarelli, who became head of Contracting and Marketing Controlling. Powers, was responsible for day-to-day management of the groups in both locations. (*Id.*; Tab 87, 1/27/05 Berkle Dep. Ex. 139, TXEX00810 (Budget 1999 Org. Chart))

79. Fulton, King, and Ciarelli provided an additional line-of-sight in the organization, but Roxane employees continued to handle the day-to-day operations of its brand and branded generic lines, including sales and marketing. (Tab 2, 10/31/08 Berkle Dep. 59-60 ("Those people within the Roxane business entity did report functionally to designated people within the BIPI organization, but the day-to-day operations were still conducted by Roxane people."); *Id.* 191-192 ("it made sense to combine . . . at certain levels the reporting relationship to . . . allow Roxane to benefit from the expertise within BIPI . . . I emphasize that the day-to-day

operations were conducted for the Roxane . . . branded generic products within the Roxane structure.”))

80. In 2000, the decision was made to divest Roxane’s palliative care and HIV line so that it could focus its business on generic products. Marketing operations for the palliative care drugs began to wind down, and at the end of 2000, the sales force dissolved and Roxane no longer had sales people promoting those products. (Tab 21, 5/21/08 Shaffer Dep. 225-226, 355-356; Tab 10, King Dep. 197) Roxane also stopped promoting Viramune, a brand name HIV drug that it licensed from BIPI. Viramune was transferred back to BIPI in 2001. (Tab 42, BOEH04600348-52, BOEH04600353-62 (Roxane Unanimous Consents); Tab 15, McIntyre Dep. 158-159)

81. On September 28, 2001, Roxane divested Roxicodone, Oramorph, Roxanol, and several other palliative care drugs to Elan Pharmaceuticals pursuant to an Asset Purchase Agreement. (Tab 53, BOEH01046045-6092 (Elan Asset Purchase Agreement); (Tab 42, BOEH04600369-74 (Roxane Unanimous Consents)) Roxane booked a \$200 million payment from Elan for the divested drugs. (Tab 48, BOEH02675446-72 at 50-52, 58 (Commentary To The Financial Statements For Year End 12/31/01))

82. From this point on, Roxane’s product line was almost exclusively generic and BIPI-based employees provided no more support for Roxane’s marketing or sales. (Tab 2, 10/31/08 Berkle Dep. at 229; Tab 1, 1/27/05 Berkle Dep. at 155)

## **V. Testimony of Professor Jonathan R. Macey**

83. Jonathan Macey is the Sam Harris Professor of Corporate Law, Corporate Finance, and Securities Law at the Yale Law School, and Professor in the Yale School of Management. He currently serves as Deputy Dean of the Yale Law School, and is a member of the Board of Directors of the Yale Law School Center for the Study of Corporate Governance

and a Member of the Faculty Advisory Group of Yale's Millstein Center for Corporate Governance Performance. Professor Macey has served on the boards of directors of numerous companies, has taught many joint business and law school classes on corporate governance and business organizations, and has written extensively on those topics. (Tab 88, Macey Dep. Ex. 1 (Macey CV))

84. His areas of expertise are "corporate governance, corporate control, ordinary and standard business practices among, parent, subsidiaries and affiliate corporations, and economic and public policy related to corporate groups and relationships among parent, subsidiary and affiliate corporations." (Tab 11, 5/19/09 Macey Dep. 45) He has studied, written and taught extensively on these topics. (Tab 88, Macey Ex. 1 (Macey CV))

85. Professor Macey analyzed the corporate governance issues related to the interactions and relationships between the BIC, BIPI and Roxane, including whether the companies "operated as separate and independent corporate entities" and whether the "relationships were consistent with ordinary and customary business practices" as well as sound public policy. (Tab 11, Macey Dep. 47-48) In the course of his work he looked at, among other information, the history of the companies, the relationships and interactions between the entities and how they evolved over time, the corporate formalities followed by the companies and the capitalization and financial condition of Roxane. (*Id.* 53-54)

86. Professor Macey's opinion, based on "[his] research and practical experience in the area of corporate governance" is that "the relationship between BIC, as a parent holding company, and Roxane was well within the normal range with respect to corporate governance relationships and corporate formalities and corporate separateness and maintaining an actual corporate identity . . . with respect to both of those entities." On this same basis,

Professor Macey's opinion is that the corporate relationships between BIPI and BIC, and BIPI and Roxane, are normal and typical. (*Id.* 51-52)

87. In reaching his opinion that the relationships among the defendants were normal and typical, Professor Macey's methodology involved "comparing the actual interactions among these companies . . . with ordinary and customary business practice and . . . industry norm" and then looking at the "public policy benefits and costs associated with those" to determine whether the relationships among BIC, BIPI, and Roxane were "one, normal and consistent with . . . U.S. corporate practice, and two, whether they presented any . . . externality or cost or policy issues." (*Id.* 54-55) According to Professor Macey, corporate relationships are considered normal and typical if "they are consistent with standard practice with what we observe other similarly situated, similarly organized corporations doing . . . [a]nd two, whether there are any kind of special problems associated with a particular form of or particular pattern of behavior among parents and subsidiaries or sibling corporations." (*Id.* 55)

88. Professor Macey's basis for what constitutes a normal and typical corporate relationship is "what corporations actually do." Professor Macey testified "I study corporate relationships, I study corporate groups, and I study the interactions among these groups from a wide variety of perspectives and so it's a matter of my research and experience as to . . . what it is that we observe in . . . the landscape of U.S. business." (*Id.* 58-59)

89. Professor Macey testified that it is normal and typical for holding companies, or one subsidiary in a corporate family – like BIPI – to provide shared services for the other subsidiaries, such as legal IT, financial and accounting services. (*Id.* 68-69)

90. Professor Macey also noted that it is "beyond routine . . . for personnel within subsidiaries to be actively involved in the management and operations of sibling companies



because . . . it's extremely common to see people in these various corporate groups wear a multitude of hats.” (*Id.* 74) It is also “extremely common for subsidiary companies to contract with each other and to have interactions of a variety of kinds. . . .” (*Id.*) Both practices are common because it allows the “expertise of one . . . or the services of one” to be “utilized for the benefit” of another.” (*Id.* 74-75)

91. Based on this benchmark of typical corporate relationships, Professor Macey concluded that when a BIPI officer, Sheldon Berkle, held certain oversight responsibilities over certain Roxane products, “he wasn’t really doing anything by or on behalf of BIPI” and would not be characterized as a BIPI agent. (*Id.* 78-79) Professor Macey concluded that “he was wearing two hats and he was operating as a Roxane person.” (*Id.* 79)

92. Professor Macey observed that the particular facts of this case made it “extremely easy to tell, for example, when Mr. Berkle is acting for Roxane and when Mr. Berkle is acting for BIPI”, because Roxane’s products were separate and distinct from BIPI’s drugs. As such, Mr. Berkle’s decisions regarding particular drugs would not apply to both companies. (*Id.* 81-82)

93. Professor Macey determined that certain BIPI employees who were given responsibilities with regard to Roxane’s brand and branded generic products in 1998, “took on . . . a second hat” and “became agents of Roxane.” (*Id.* 159-161) To the extent that individuals such as Mr. Leonetti, Mr. Fulton, Mr. Ciarelli, and Mr. King were involved in the high level supervision of Roxane’s brand and branded generic products, in that capacity, “they were acting as agents of Roxane.” (*Id.* 166-167) Professor Macey noted that “virtually without exception one observes these kind of dual relationships which involve somebody who is accepting one paycheck from one company, who is kind of seconded . . . or acting as an agent wearing a second

hat with respect to a second company.” (*Id.* 167) Macey also testified that in those situations where employees serve dual roles at two companies, the “overwhelming business practice in the United States is to have people receive a single paycheck.” (Tab 12, 5/20/09 Macey Dep. 269-270)

94. Professor Macey testified that in some situations it could be difficult to tell which hat an employee is wearing at a given time, but here “we can tell on whose behalf these people are operating as agent because we know, we can see whose company’s products they were involved with . . .” (Tab 11, 5/19/09 Macey Dep. 167-68)

95. Professor Macey also examined Roxane’s balance sheets and profit and loss statements to determine whether Roxane was adequately capitalized over time. (Tab 12, 5/20/09 Macey Dep. 297) Professor Macey has been qualified to serve as a member of a public corporation’s audit committee, and in that capacity, is responsible for reviewing the company’s financial statements and ensuring they are in accordance with appropriate accounting principles. (*Id.* 299) In this case, Professor Macey evaluated a number of different factors relevant to a company’s level of capitalization, such as whether there were incursions on Roxane’s initial capitalization and capital surplus, the amount of Roxane’s retained earnings, Roxane’s dividend policy, and Roxane’s average debt-to-equity ratio compared with average debt-to-equity ratios among other pharmaceutical firms. (*Id.* 318-20, 336-337). Professor Macey calculated Roxane’s average retained earnings between 1995 and 2005, and Roxane’s average dividend payments between 1995 and 2005. (*Id.* 338) Based on this analysis, Professor Macey concluded that Roxane was sufficiently capitalized during the relevant time period. (*Id.* 296, 311-312)

96. Professor Macey’s opinion, based on the totality of the record, is that Roxane operated as an independent company. (Tab 11, 5/19/09 Macey Dep. 87-88) As a distinct

corporate entity, Professor Macey determined that Roxane did “maintain operational control over its business” and that included “control over the pricing and marketing of its products.”

(*Id.* 122-123)

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Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by sending on June 29, 2009, a copy to LexisNexis File and Serve for posting and notification to all parties.

/s/ John W. Reale

John W. Reale